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PATENT

Atty. Docket No.
ARC 2863 N1

J&J Ref.: AR08025US
(AR02863-US-CNT1)

Date: May 20, 2005 By: [Signature]
Lois E. Miller

CN 27777

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Suneel K. GUPTA et al.

Serial No.: 09/801,443

Filed: March 7, 2001

For: OXYBUTYNIN THERAPY

Group Art Unit: to be assigned

Examiner: to be assigned

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☐ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the

mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☒ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

☐ Statement in Accordance with §1.97(e) (attached); or

☒ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☐ There are no listed references which are not in the English language.

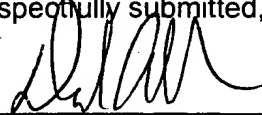
☐ The relevance of those listed references which are not in the English language is as follows:

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

Respectfully submitted,



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Application Number	09/801,443
Filing Date	03/07/2001
First Named Inventor	Suneel K. GUPTA
Group Art Unit	1615
Examiner Name	TRAN, Susan T.
Attorney Docket Number	ARC 2863 N1

Substitute for form 1449A-PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Application Number	09/801,443
Filing Date	03/07/2001
First Named Inventor	Suneel K. GUPTA
Group Art Unit	1615
Examiner Name	TRAN, Susan T
Attorney Docket Number	ARC 2863 N1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
	AA	2,799,241		WURSTER	07/16/1957	
	AB	3,845,770		THEEUWES et al.	11/05/1974	
	AC	3,916,899		THEEUWES et al.	11/04/1975	
	AD	4,063,064		SAUNDERS et al.	12/13/1977	
	AE	4,088,864		THEEUWES et al.	05/09/1978	
	AE	4,200,098		AYER et al.	04/29/1980	
	AC	4,285,987		AYER et al.	08/25/1981	
	AH	4,327,725		CORTESE et al.	05/04/1982	
	AI	4,612,008		WONG et al.	09/16/1986	
	AJ	4,783,337		WONG et al.	11/08/1988	
	AK	4,816,263		AYER et al.	03/28/1989	
	AL	4,863,456		STEPHENS et al.	09/05/1989	
	AM	4,902,514		BARCLAY et al.	02/20/1990	
	AN	5,480,651		CALLAWAY	01/02/1996	
	AO	5,674,895		GUITTARD et al.	10/07/1997	
	AP	5,840,754		GUITTARD et al.	11/24/1998	
	AQ	6,124,335		GUITTARD et al.	09/26/2000	
	AR	6,262,115		GUITTARD et al.	07/17/2001	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵				
	AS	WO	96/12477	A1	LEIRAS OY (Rantala et al.)	05/02/1996		
	AT	WO	98/43555	A1	Point Biomedical Corp.	10/08/1998		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A-PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 2 of 2		Application Number 09/801,443 Filing Date 03/07/2001 First Named Inventor Suneel K. GUPTA Group Art Unit 1615 Examiner Name TRAN, Susan T Attorney Docket Number ARC 2863 N1	
'OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T ²
	AU	BENZIGER, David P. et al., "Differential Effects of Food on the Bioavailability of Controlled-Release Oxycodone Tablets and Immediate-Release Oxycodone Solution", <u>Journal of Pharmaceutical Sciences</u> , 85(4):407-410, 1996	
	AV	CHUNG, Menger et al., "Clinical Pharmacokinetics of Nifedipine Gastrointestinal Therapeutic System", <u>The American Journal of Medicine</u> , 83:10-14, 1987	
	AW	GRAFTON, P., "General principles for designing with plastics", <u>Modern Plastics Encyclopedia</u> , 46:62-70, 1969.	
	AX	LUKKARI, Eeva, et al., Effect of time interval between food and drug ingestion on the absorption of oxybutynin from a controlled-release tablet, <u>Pharmacol. & Toxicology</u> , 81(1):31-34, 1997	
	AY	LUKKARI, Eeva et al., "Effect of food on the bioavailability of oxybutynin from a controlled release tablet," <u>Eur. J. Pharmacology</u> , 50:221-223, 1996	
	AZ	FELMEISTER, Alvin,, "Powders," <u>Remington's Pharmaceutical Sciences</u> , 14 th Edition, Mack Publishing Co., Ch. 86, pp. 1626-1648, 1970.	
	BA	MASSAD, Charlotte A. et al., "The pharmacokinetics of intravesical and oral oxybutynin chloride", <u>J. Urology</u> , 148:595-597, August 1992 .	
	BB	NILSSON, Carl Gustaf et al., "Comparison of a 10-mg controlled release oxybutynin tablet with a 5-mg oxybutynin tablet in urge incontinent patients", <u>Nerol Urolyn</u> , 16(6):533-542, 1997.	
	BC	SATHYAN, Gayatri et al., "Effect of OROS® controlled-release delivery on the pharmacokinetics and pharmacodynamics of oxybutynin chloride", <u>Br. J Clin. Pharmacol</u> , 52:409-417, 2001.	
	BD	WALDECK, Kristen et al., "Comparison of oxybutynin and its active metabolite, N-desethyl-oxybutynin, in the human detrusor and parotid gland", <u>J. Urology</u> , 157(3):1093-1097, 1997.	
	BE	WPI / Derwent Database, "Pharmaceutical preparation prolong action urine incontinence comprise sustained release chloride pharmaceutical composition sustained release coating film non water soluble polymer ethylcellulose", Abstract of JP 05-339151, (Kodama KK), 12/21/1993	
	BF	WURSTER, Dale E., "Air-Suspension Technique of Coating Drug Particles", <u>J. Am. Pharm. Assoc</u> , 48(8):451-454, 1959	
	BG	WURSTER, Dale E., "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II", <u>J. Am. Pharm. Assoc</u> , 49(2):82-84, 1960	
	BH	YANG, Libo et al, "Modulation of Diclofenac Release From a Totally Soluble Controlled Release Drug Delivery System", <u>Journal of Controlled Release</u> , 44:135-140, 1997.	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. ⁶ If possible. ⁷ Applicant is to place a check mark here if English language Translation is attached.

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